510(K) SUMMARY

1. Administrative Information

Name:	Irvine Biomedical, Inc. a St. Jude Medical Company
Address:	2375 Morse Avenue Irvine, CA 92614
Phone:	949-769-5053
Fax:	877-482-7739
Contact Person:	Jennifer Correa Regulatory Affairs Specialist II
Date:	December 18, 2013

2. Device Information

Trade Name of Device:	ViewFlex Xtra ICE Catheter
Common Name:	ICE Catheter
Regulation Name:	870.1200, Diagnostic Intravascular Catheter
Product Codes:	OBJ

3. Predicate Device Information

1) ViewFlex Xtra ICE Catheter (Irvine Biomedical, Inc. a St. Jude Medical Company) – K121381 cleared June 7, 2012
2) AcuNav Diagnostic Ultrasound Catheter (Siemens Medical Solutions USA, Inc.) – K071234 cleared June 29, 2007

4. Device Description

The ViewFlex Xtra ICE Catheter is inserted into the heart via intravascular access. The ViewFlex Xtra is a sterile, single use, temporary, intracardiac ultrasound catheter indicated for use in adult and adolescent pediatric patients. The ViewFlex catheter shaft is a 9 French catheter constructed with radiopaque tubing with a useable length of 90 cm. The shaft is compatible with a 10 French or larger introducer for insertion into the femoral or jugular veins. The catheter tip is a 64-element linear phased array transducer housed in silicone. The distal portion of the shaft is deflectable in four directions allowing for left-to-right and anterior-to-posterior deflection. The handle of the device has two deflection mechanisms that correspond with the movement of the distal shaft in the four planes of movement. The ViewFlex Xtra is compatible with ViewMate II, ViewMate Z and Philips CX50 ultrasound consoles.

5. Intended Use

The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures; blood flow and other devices within the heart.

6. Technological Characteristics

The design, technological characteristics and materials of the proposed ViewFlex Xtra ICE Catheter are identical to the predicate, cleared ViewFlex Xtra ICE Catheter. There have been no device changes.

7. Summary of Non-clinical Testing

There have been no device changes and no changes to the visualization location. This submission is to expand the current indications for use to include visualizing other devices within the heart. Demonstration of the ability of the ViewFlex Xtra ICE catheter to image devices in the heart was provided by referencing image quality testing and data for the cleared ViewFlex Xtra ICE catheter (K121381) and images collected during the use of the predicates for visualizing other devices within the heart. The Instructions for Use was updated to include examples of types of devices which could be imaged using the ViewFlex Xtra ICE catheter and that the use of the images is limited to visualization with no direct or indirect diagnostic use.

8. Substantial Equivalence Conclusion

The proposed ViewFlex Xtra ICE Catheter in this submission is substantially equivalent to previously cleared St. Jude Medical's ViewFlex Xtra ICE Catheter (K121381, June 7, 2012) and Siemen's AcuNav Diagnostic Ultrasound Catheter (K071234, June 29, 2007). Differences between the devices do not raise issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 19, 2014

Irvine Biomedical, Inc. A St. Jude Medical Company
Jennifer Correa
2375 Morse Avenue
Irvine, CA 92614 US

Re: K133853
Trade/Device Name: VIEWFLEX XTRA ICE CATHETER
Regulation Number: 21 CFR 870.1200
Regulation Name: Ice Catheter
Regulatory Class: Class II
Product Code: OBJ
Dated: April 11, 2014
Received: April 14, 2014

Dear Jennifer Correa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

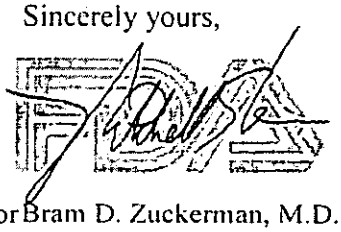
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ViewFlex Xtra ICE Catheter

Premarket Notification 510(k)

ST. JUDE MEDICAL

Indications for Use

510(k) Number (if known): K133853

Device Name: ViewFlex Xtra ICE Catheter

Indications for Use:

The ViewFlex Xtra ICE Catheter is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures, blood flow and other devices within the heart.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Date: 2014.05.19 15:28:33 -04'00'
